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EXAMINER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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patentadministrator@clarkelbing.com

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3-7 and 11 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Laus et al. (Journal of Controlled Release, 2001, 72:225-309) in view of Betti et al. (Vaccine, 2001, 19:2308-3419), Caputo et al. (Vaccine, 2003, 21:1103-1111), Caselli et al. (Journal of Immunology, 1999, 162:5631-5638) and O'Hagan et al. (WO 98/033487).

The claims are directed to a microparticle comprising:

(a) a core which comprises a water insoluble polymer or copolymer, and

(b) a shell which comprises a hydrophilic polymer or copolymer and functional groups which are ionic or ionisable; said microparticle having a disease-associated antigen adsorbed at the external surface.

Laus et al. discloses a microparticle comprising: (a) a core which comprises a water insoluble polymer or copolymer, and (b) a shell which comprises a hydrophilic polymer or copolymer and functional groups which are ionic or ionisable; said microparticle having BSA adsorbed at the external surface (see the entire document, especially the results and discussion). The microspheres are made of polystyrene or polymethylmethacrylate with hemisuccinated polyvinylalcohol or Eudragit L100/55 as the hydrophilic copolymer. The microspheres range in size from 0.5 to 20 μm.

Laus et al. does not teach a disease associated antigen adsorbed to the microparticles. However, Laus et al. teaches that the surface of the microparticles is protein friendly (i.e., proteins are easily immobilized on the surface) and that the microspheres can be used for immobilizing high amounts of protein for protein delivery systems where the protein is protected from degradation (see page 283). In addition, Betti et al., Caputo et al. (2003) and Caselli et al. teach the use of HIV Tat as a vaccine candidate and the use of copolymers to deliver HIV Tat DNA to a subject. Furthermore, it is well known in the art to use microparticles with adsorbed HIV antigens as vaccines (see, for example, O'Hagan et al. O'Hagan et al. used microparticles to deliver HIV p24 gag and to induce cytotoxic T-lymphocyte activity, see page 14, line 10 to page 15, line 13, and Examples 9 and 10 of O'Hagan et al.).

Therefore, it would have been obvious to one of ordinary skill in the art to substitute any other protein, including disease-associated antigens such as Tat, on the surface of the microparticle of Laus et al. and the results would have been predictable (i.e., a microparticle with protein adsorbed on the surface). Further, in view of Laus et al.'s suggestion to use the microspheres as protein delivery vehicles, the teachings of O'Hagan et al. to use protein coated microparticles to induce an immune response, and the teachings of Betti et al., Caputo et al. (2003) and Caselli et al. that HIV Tat is a vaccine candidate which can be delivered via copolymers, it would have been obvious for one of ordinary skill in the art to use the protein coated microspheres of Laus et al. to generate an immune response in a subject against Tat.

Response to Arguments

In the reply dated August 17, 2009, applicants argue that the claims are directed to Tat protein (not Tat DNA) and that the inventors have shown that Tat protein unexpectedly becomes stable once adsorbed onto microparticles. These arguments have been fully considered, but not found persuasive.

As stated above, Laus et al. discloses the claimed microparticles and teaches that the microparticles are "protein friendly" (i.e., proteins are easily immobilized on the surface) and that the microspheres can be used for immobilizing high amounts of protein for protein delivery systems where the protein is protected from degradation (see page 283).

O'Hagen et al. uses microparticles to deliver various antigens vaccine purposes. O'Hagen et al. also teaches that antigens that can be delivered can be derived from other viruses, such as without limitation, proteins from members of the families Picornaviridae (e.g., polioviruses, etc.); Caliciviridae; Togaviridae (e.g., rubella virus, dengue virus, etc.) ; Flaviviridae; Coronaviridae; Reoviridae; Birnaviridae; Rhabodoviridae (e.g., rabies virus, etc.); Filoviridae; Paramyxoviridae (e.g., mumps virus, measles virus, respiratory syncytial virus, etc.) ; Orthomyxoviridae (e.g., influenza virus types A, B and C, etc.); Bunyaviridae; Arenaviridae; Retroviradae (e.g., HTLV-I; HTLV-II; HIV-1 (also known as HTLV-III, LAV, ARV, hTLR, etc.)), including but not limited to antigens from the isolates HIV_{IIIb}, HIV_{SF2}, HIV_{LAV}, HIV_{LAI}, HIV_{MN}); HIV-1_{CM235}, HIV-I_{US4}; HIV-2; simian immunodeficiency virus (SIV) among others. O'Hagen et al. also states that "the invention is equally applicable to other immunogenic proteins derived from any of the various HIV isolates, including any of the various envelope proteins." (See page 14, line 10 to page 15, line 13).

Thus, O'Hagen et al. teaches that any antigens from the viruses (e.g., HIV) listed can be used. It is well known in the art that Tat (DNA and protein) is an HIV antigen commonly used for vaccine purposes (see, for example, Betti et al. (Tat DNA), Caputo et al. (Tat DNA), Caselli et al. (Tat DNA and Tat protein)). See also, Feng et al. (U.S. Patent Application No. 6,753,015), which teaches the delivery of Tat protein by microparticles (col. 13, lines 55-60).

Thus, it would be obvious to one of ordinary skill in the art to take the suggestions and teachings of the prior art, as outlined above, and substitute Tat and

any other viral antigens on the microparticle of Laus et al. for protein delivery as taught by Laus et al. (i.e., the microspheres can be used for immobilizing high amounts of protein for protein delivery systems where the protein is protected from degradation).

The "unexpected properties" are properties that are also possessed by the prior art microparticles. As outlined above, it would have been obvious to use the copolymer particles to deliver Tat protein to a subject for vaccine purposes. Thus, the "unexpected properties" (e.g., increased stability of Tat) are an inherent feature of the art-recognized copolymer particles.

According to the MPEP "the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

In addition, the inherent feature need not be recognized at the time of invention. There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. Schering Corp. v. Geneva Pharm. Inc., 339 F.3d 373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003) (rejecting the contention that inherent anticipation requires recognition by a person of ordinary skill in the art before the critical

date and allowing expert testimony with respect to post-critical date clinical trials to show inherency).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3-7 and 11 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 and 10-15 of copending Application No. 10/577,973. Although the conflicting claims are not identical, they are not patentably distinct from each other because they relate to the same inventive concept.

The subgenus claims of copending application 10/577,973 anticipate the instant genus claims, and a patent to the instant genus claims would, necessarily, extend the

rights of the a patent granted to the sub-genus claims should both applications issue as a patent.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NICOLE KINSEY WHITE whose telephone number is (571)272-9943. The examiner can normally be reached on Monday through Friday from 9:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicole Kinsey White/
Examiner, Art Unit 1648

/Stacy B Chen/
Primary Examiner, Art Unit 1648